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C014CIP/DIV2

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Not Yet Assigned  
Group Art Unit : 1644  
Applicants : Michael J. Yellin et al.  
Serial No. : 09/342,314  
Filed : June 29, 1999  
For : THERAPEUTIC APPLICATIONS FOR THE ANTI-T-BAM  
(CD40-L) MONOCLONAL ANTIBODY 5c8

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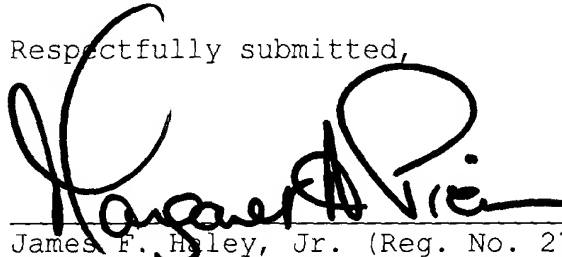
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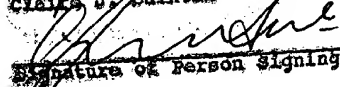
Respectfully submitted,



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INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b) applicants  
make of record the following documents:

1. United States patent: 5,474,771  
Patentee: Lederman et al.  
Issue date: December 12, 1995
2. United States patent: 5,540,926  
Patentee: Aruffo et al.  
Issue date: July 30, 1996.
3. United States patent: 5,674,492  
Patentee: Armitage et al.  
Issue date: October 7, 1997.
4. United States patent: 5,677,165

Patentee: de Boer et al.  
Issue date: October 14, 1997.

5. United States patent: 5,683,693  
Patentee: Noelle et al.  
Issue date: November 4, 1997.
6. United States patent: 5,747,037  
Patentee: Noelle et al.  
Issue date: May 5, 1998.
7. United States patent: 5,833,987  
Patentee: Noelle et al.  
Issue date: November 10, 1998
8. United States patent 5,869,049  
Patentee: Noelle et al.  
Issue date: February 9, 1999
9. United States patent 5,876,718  
Patentee: Noelle et al.  
Issue date: March 2, 1999
10. United States patent 5,876,950  
Patentee: Siadak et al.  
Issue date: March 2, 1999
11. United States patent 5,902,585  
Patentee: Noelle et al.  
Issue date: May 11, 1999
12. United States patent 5,916,560  
Patentee: Larsen et al.  
Issue date: June 29, 1999
13. United States patent 5,942,229  
Patentee: Noelle et al.  
Issue date: August 24, 1999
14. United States patent 5,945,513  
Patentee: Aruffo et al.  
Issue date: August 31, 1999
15. United States patent 5,961,974  
Patentee: Armitage et al.  
Issue date: October 5, 1999
16. United States patent 5,962,406  
Patentee: Armitage et al.

Issue date: October 5, 1999

17. United States patent 5,981,724  
Patentee: Armitage et al.  
Issue date: November 9, 1999
18. United States patent 5,993,816  
Patentee: Lederman et al.  
Issue date: November 30, 1999
19. United States patent 6,001,358  
Patentee: Black et al.  
Issue date: December 14, 1999
20. PCT patent application: WO 93/08207  
Publication date: April 29, 1993.
21. PCT patent application: WO 93/09812  
Publication date: May 27, 1993.
22. PCT patent application: WO 94/04570  
Publication date: March 3, 1994.
23. PCT patent application: WO 95/06481  
Publication date: March 9, 1995.
24. PCT patent application: WO 95/06666  
Publication date: March 9, 1995.
25. PCT patent application: WO 95/09653  
Publication date: April 13, 1995.
26. PCT patent application: WO 96/23071  
Publication date: August 1, 1996.
27. PCT patent application: WO 96/28568  
Publication date: September 19, 1996.
28. PCT patent application: WO 96/40246  
Publication date: December 19, 1996.
29. PCT patent application: WO 97/17446  
Publication date: May 15, 1997.

### Articles

- Alderson, M.R. et al. "CD40 Expression By Human Monocytes: Regulation By Cytokines And Activation Of Monocytes By The Ligand For CD40", *J. Exp. Med.* 178:669-674 (1993).
- Bajorath J. et al. "Identification of Residues on CD40 and Its Ligand Which Are Critical for the Receptor-Ligand Interaction", *Biochemistry* 34:1833-1844 (1995).
- Banchereau J. et al. "The CD40 Antigen and its Ligand", *Annual Rev. Immunol.* 12:881-922 (1994).
- Biancone, L. et al. "Inhibition of the CD40-CD40Ligand Pathway Prevents Murine Membranous Glomerulonephritis", *Kidney Intl.* 48:458-468 (1995).
- Buhlmann, J.E. et al. "Therapeutic Potential For Blockade of the CD40 Ligand, gp39", *J. Clin. Immunol.* 16:83-89 (1996).
- Carbone, A. et al. "Expression of Functional CD40 Antigen on Reed-Sternberg Cells and Hodgkin's Disease Cell Lines", *Blood* 85(3):780-789 (1995).
- Clark, E.A. et al. "Activation of Human B Cells Mediated Through Two Distinct Cell Surface Differentiation Antigens, Bp35 and Bp50", *Proc. Natl. Acad. Sci., USA* 83:4494-4498 (1986).
- Cleary, A. M. et al. "Opposing Roles of CD95 (Fas/APO-1) and CD40 in the Death and Rescue of Human Low Density Tonsillar B Cells", *J. Immunol.* 155:3329-3337 (1995).
- Durie, F.H. et al. "The Role of CD40 and its Ligand (gp39) in Peripheral and Central Tolerance and its Contribution to Autoimmune Disease", *Res. Immunol.* 145:200-205 (1994).
- Durie, F.H. et al. "The Role of CD40 in the Regulation of Humoral and Cell-Mediated Immunity", *Immunol. Today* 15:406-411 (1994).
- Durie, F.H. et al. "Prevention of Collagen-Induced Arthritis With An Antibody to gp39, the Ligand for CD40", *Science* 261:1328-1330 (1993).

- Fanslow W. C. et al. "Soluble Forms of CD40 Inhibit Biologic Responses of Human B Cells", *J. Immunol.* 149:655-660 (1992).
- Freudenthal, P.S. et al. "The Distinct Surface of Human Blood Dendritic Cells, As Observed After An Improved Isolation Method", *Proc. Natl. Acad. Sci., USA* 87:7698-7702 (1990).
- Galy, A.H.M. et al. "CD40 is Functionally Expressed on Human Thymic Epithelial Cells", *J. Immunol.* 149:775-782 (1992).
- Gray, D. et al "Memory B Cell Development But Not Germinal Center Formation is Impaired by In Vivo Blockade of CD40-CD40 Ligand Interaction", *J. Exp. Med.* 180:141-154 (1994).
- Hasbold, J. et al. "Properties of Mouse CD40: Cellular Distribution of CD40 and B Cell Activation by Monoclonal Anti-Mouse CD40 Antibodies", *Eur. J. Of Immunol.* 24:1835-1842 (1994).
- Hollenbaugh, D. et al. "Expression of Functional CD40 by Vascular Endothelial Cells", *J. Exp. Med.* 182:33-40 (1995).
- Karmann, K. et al. "CD40 on Human Endothelial Cells: Inducibility by Cytokines and Functional Regulation of Adhesion Molecule Expression", *Proc. Natl. Acad. Sci., USA* 92:4342-4346 (1995).
- Karpusas, M. et al. "2 Å Crystal Structure of an Extracellular Fragment of Human CD40 Ligand", *Structure* 3(10): 1031-1039 (1995).
- Kuntz, I.D. "Structure-Based Strategies for Drug Design and Discovery", *Science* 257:1078-1082 (1992).
- Kuwana, M. et al. "T and B Cell Collaboration is Essential for the Autoantibody Response to DNA Topoisomerase I in Systemic Sclerosis", *J. Immunol.* 155:2703-2714 (1995).
- Laman, J.D. et al. "The Role of GP39 (CD40 Ligand) in EAE and MS", *J. Neuroimmunology* 54:175 (1994).
- Larsen, C.P. et al. "CD40-gp39 Interactions Play A Critical Role During Allograft Rejection", *Transplantation* 61:4-9 (1996).
- Law, C-L. et al. "Analysis of Expression and Function of CD40 on Normal and Leukemic Human B Cell Precursors", *Leukemia* 4(11):732-738 (1990).

Lederman, S. et al. "The Understanding of Contact-Dependent T-Cell Helper Function in Molecular, Cellular and Physiological Detail", *Res. Immunol.* 145:215-222 (1994).

Mohan, C. et al. "Interaction Between CD40 and Its Ligand gp39 in the Development of Murine Lupus Nephritis", *J. Immunol.* 154:1470-1480 (1995).

Merck Manual of Diagnosis And Therapy, 16th Ed. "Idiopathic Infiltrative Diseases Of The Lungs", Merck Research Laboratories, Rahway, NJ 718-720 (1992).

O'Grady, J.T. et al. "CD40 Expression in Hodgkin's Disease", *Am. J. Of Pathology* 144:(1):2126 (1994).

Paulie, S. et al. "A p50 Surface Antigen Restricted to Human Urinary Bladder Carcinomas and B Lymphocytes", *Cancer Immunol. Immunother.* 20:23-28 (1985).

Potocnik, A.J. et al. "Expression of Activation Antigens on T Cells in Rheumatoid Arthritis Patients", *Scand. J. Immunol.* 31:213-224 (1990).

Stüber, E. et al. "Blocking The CD40L-CD40 Interaction In Vivo Specifically Prevents the Priming of T Helper 1 Cells Through the Inhibition of Interleukin 12 Secretion", *J. Exp. Med.* 183: 693-698 (1996).

Uckun, F.M. et al. "Temporal Association of CD40 Antigen Expression With Discrete Stages of Human B-Cell Ontogeny and the Efficacy Of Anti-CD40 Immunotoxins Against Clonogenic B-Lineage Acute Lymphoblastic Leukemia As Well As B-Lineage Non-Hodgkin's Lymphoma Cells", *Blood* 76(12):2449-2456 (1990).

Urashima, M. et al. "CD40 Ligand Triggered Interleukin-6 Secretion In Multiple Myeloma", *Blood* 85:1903-1912 (1995).

Valent, P. et al. "Further Characterization Of Surface Membrane Structures Expressed On Human Basophils And Mast Cells", *Int. Arch. Allergy Appl. Immunol.* 91:198-203 (1990).

Westendorf, J.J. et al. "Molecular And Biological Role Of CD40 In Multiple Myeloma", *Curr. Top. Microbiol. Immunol.* 194:63-72 (1995).

Westendorf, J.J. et al. "CD40 Expressions In Malignant Plasma Cells", *J. Of Immunol.* 152:117-128 (1994).



Yellin, M.J. et al. "Function of CD40 Molecules Expressed on Cultured Synovial Membrane Fibroblasts" *FASEB J.* (March 10, 1995) 9(4):A774, Abstract No. 4483 - Oral presentation at FASEB Meeting in Atlanta, Georgia" (1995).

Yellin, M.J. et al. "Human Fibroblasts and Endothelial Cells Express CD40 and are Activated by CD40L+ Cells," Poster session at 9th International Congress of Immunology meeting in San Francisco, California (Abstract available July 23, 1995).

Yellin, M.J. et al. "Ligation Of CD40 On Fibroblasts Induces CD54 (ICAM-1) and CD106 (VCAM-1) Upregulation And IL-6 Production And Proliferation," *J. Leukocyte Biology* 58:209-216 (1995).

Yellin, M.J. et al. "Functional Interactions Of T Cells With Endothelial Cells: The Role Of CD40L-CD40-Mediated Signals," *J. Exp. Med.* 182:1857-1864 (1995).

Yellin M. J. et al. "In situ Characterization of CD40L and CD40 Expression in Glomerulonephritis (GN)", Abstract May 1, 1996: ASBMB/ASIP/AAL Joint Meeting.

Yellin M. J. et al. "Function of CD40 Molecules Expressed on Cultured Synovial Membrane Fibroblasts", *FASEB J.* 9:A774 - Abstract No. 4483 (1995).

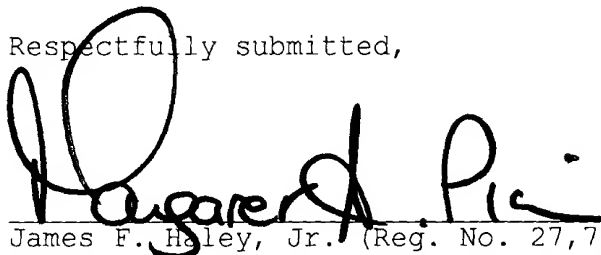
Young, L.S. et al. "Identification Of A Human Epithelial Cell Surface Protein Sharing An Epitope With The C3d/Epstein-Barr Virus Receptor Molecule Of B Lymphocytes," *Int. J. Cancer* 43:786-794 (1989).

For the Examiner's convenience, the above-mentioned documents are listed on the accompanying Form PTO-1449.

Applicants respectfully request that the above-cited documents be (1) fully considered by the Examiner during the continued examination of this application and (2) printed on any patent issuing from this application. Applicants also request that a copy of the enclosed Form PTO-1449, duly initialed by the Examiner, be forwarded to the undersigned with the next communication.

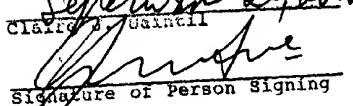
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Respectfully submitted,



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